

K97 0202
510(k) SUMMARY

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NAME OF FIRM: DePuy ACE Medical Company
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TRADE NAME DePuy ACE AIM® Titanium Tibial Nail

COMMON NAME Intramedullary Bone Fixation Rod

CLASSIFICATION 888.3020 Intramedullary Fixation Rod

DEVICE PRODUCT CODE 87 HSB - *class 2*

SUBSTANTIALLY EQUIVALENT DEVICE DePuy ACE AIM® Titanium Tibial Nail

INTENDED USE:

The DePuy ACE AIM® Titanium Tibial Nail is indicated for internal fixation of tibial fractures including transverse fractures, oblique and spiral fractures, comminuted fractures, fractures with bone loss, bone transport, open fractures, corrective osteotomies, pathologic fractures, pseudoarthrosis of the tibial shaft, nonunions, malunions metaphyseal fractures and epiphyseal fractures.

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The DePuy ACE AIM® Titanium Tibial Nail is an intramedullary fixation rod for the fixation of tibial fractures. The nail has a distal bend of 2° for the nails of 10mm, 11mm, 12mm and 13mm diameters. The distal bend in the nails of 8mm and 9mm diameters is 5°. The DePuy ACE AIM® Titanium Tibial Nail has diameters from 8.0mm to 13.0mm and lengths from 25.5 cm to 43.5cm. The proximal end of the 10mm, 11mm, 12mm and 13mm nails is 13mm in diameter while the proximal end of the 8mm and 9mm nails is 11mm in diameter. The proximal end of the nail contains two 6mm cross locking screw holes which accept 5.5mm solid cortical bone screws. The distal end of the nail contains two 5.0mm holes which accept 4.5mm solid cortical bone screws. The 8mm and 9mm nails are solid while the 10mm to 13mm nails are cannulated.

The DePuy ACE AIM® Titanium Tibial Nail is manufactured from Titanium 6Al-4V ELI (ASTM standard F-136)

Comparative testing between the versions of the tibial nails was conducted on cadavers which showed that the insertion and extraction forces are decreased by reducing the distal bend for a 13mm nail. Under clinical usage, it is believed that a distal bend is necessary during insertion to reduce the likelihood of fracturing or perforating the posterior cortex. Therefore, the distal bend of the large tibial nails will be reduced to 2°.

The 8mm and 9mm nails are used in unreamed applications. Due to their small diameter, difficulty during insertion and extraction has not been encountered. Therefore, the small nails will keep the a 5° distal bend.

Based on this information, DePuy Ace believes that the modified DePuy ACE AIM® Titanium Tibial Nails are substantially equivalent to the DePuy ACE AIM® Titanium Tibial Nail previously cleared for tibial fractures.